UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF WEST VIRGINIA
AT CHARLESTON

IN RE: ETHICON, INC. PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	**Master File No. 2:12-MD-02327** **MDL No. 2327** **Wave 8** **JOSEPH R. GOODWIN** **U.S. DISTRICT JUDGE**
THIS DOCUMENT RELATES TO: **WAVE 8 CASES LISTED ON EXHIBIT A TO PLAINTIFFS' MOTION**	

DEFENDANTS' RESPONSE IN OPPOSITION TO PLAINTIFFS' MOTION TO PRECLUDE OR LIMIT OPINIONS OF MILES MURPHY, M.D.

Plaintiffs challenge Dr. Murphy's warnings opinions for Prolift, TVT and TVT-O, his opinions concerning whether Ethicon met the standard of care, his opinions regarding the design and material used in the TVT and TVT-O devices, several miscellaneous opinions regarding Prolift and seek to limit the materials he relied upon in forming his opinions. *See* Memorandum in Support of Pls.' Motion (Doc. No. 6902). Plaintiffs' Motion should be denied.

BACKGROUND

Plaintiffs do not challenge Dr. Murphy's qualifications, nor could they. Dr. Miles Murphy is Board Certified in Obstetrics and Gynecology, and has a subspecialty in Female Pelvic Medicine & Reconstructive Surgery (formerly known as Urogynecology). *See* Ex. B to Plaintiffs' Motion, Murphy (TVT, TVT-O) Report (Aug. 2018) at 1 ("TVT Report"). He has served in various capacities for the American Urogynecologic Society (AUGS) and the Society of Gynecologic Surgeons (SGS). *Id*. at 1-2. His entire practice is devoted to treating women with disorders of the pelvic floor, and includes performing, on average, 5-8 urogynecologic

surgical cases per week for the last 17 years. *Id*. at 2. He estimates that he has performed over 3000 surgeries using midurethral slings to treat stress urinary incontinence. *Id*. at 3. In addition, he performed over 1000 surgeries using the Prolift device. *See* Ex. D to Plaintiffs' Motion, Murphy (2012 Prolift) Report at 2 ("Prolift Report").

ARGUMENT

I. Dr. Murphy's opinions concerning Prolift warnings are admissible.

Plaintiffs fail to identify with any particularity what opinions they seek to preclude, choosing instead to vaguely assert that any opinion concerning the product warnings, patient brochures and marketing materials should be excluded. Pls.' Mem. at 3.[1] This argument lacks sufficient specificity and the challenge to Dr. Murphy's opinions is best reserved for trial in order to compel Plaintiffs to identify the opinions they actually seek to exclude. As noted by this Court repeatedly in Wave 1 *Daubert* orders, the Court "will not make speculative or advisory rulings" where the movant has failed to identify "the specific expert testimony to be excluded." *See, e.g., In re Ethicon, Inc.*, 2016 WL 4944331, *6 (S.D. W. Va. Aug. 31, 2016).

In addition, Plaintiffs argue that Dr. Murphy's opinions concerning Prolift warnings are "net opinions." Pls.' Mem. at 3. The net opinion rule is not a standard under *Daubert*, but rather is particular to New Jersey law. Under *Daubert*, expert testimony is admissible if the expert is qualified and if his or her expert testimony is reliable and relevant. Fed. R. Evid. 702; *see also Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579, 597 (1993). An expert may be

[1] Defendants acknowledge that this Court has previously held that an expert may not state his opinion using legal terms of art, *Ramsey v. Boston Sci. Corp.*, No. 2:13-cv-15223, 2016 WL 2939526, at *2 (S.D. W.Va. May 19, 2016), nor may he opine that a particular warning label "adequately inform[s] users of the dangers associated with using the device." *Hall v. Boston Scientific Corp.*, No. 2:12-CV-08186, 2015 WL 868907, at *10 (S.D.W. Va. Feb. 27, 2015). Accordingly, Dr. Murphy will not offer the opinion that the IFUs in issue "adequately" warned of potential complications. That, however, does not preclude his opinions concerning the risks and benefits associated with the Prolift device.

qualified to offer expert testimony based on his "knowledge, skill, experience, training, or education." Fed. R. Evid. 702. Here, Dr. Murphy is qualified and his opinions are both relevant and reliable. Plaintiffs' "net opinion" argument is, therefore, irrelevant.

Finally, Plaintiffs assert that Dr. Murphy's opinions concerning the Prolift product warnings are inadmissible because he relied only on his personal opinion in assessing the product warning. Pls.' Mem. at 3. First, as noted by this Court, "doctors are fully qualified to opine on the medical facts and science regarding the risks and benefits of drugs and to compare that knowledge with what was provided in the text of labeling and warnings." *Winebarger v. Boston Scientific Corp.*, No. 2:13-CV-28892, 2015 WL 1887222, at *15 (S.D.W. Va. Apr. 24, 2015) (quoting *In re Yasmin & Yaz (Drospirenone) Prods. Liab. Litig.*, No. 3:09–md–02100, 2011 WL 6301625, at *11 (S.D. Ill. Dec.16, 2011)).

According to the FDA regulations governing warnings, a product IFU need not warn of risks that are known generally to the users of products. The FDA device regulations say that information may be omitted from labeling:

> if, but only if, the article is a device for which directions, hazards, warnings and other information are **commonly known to practitioners licensed by law to use the device**.

21 C.F.R. §801.10(c) (emphasis added); *see also Brooks v. Medtronic, Inc.*, 750 F.2d 1227, 1230 (4th Cir. 1984) (duty to warn only of dangers "not well known to the medical community."). That makes sense, for otherwise product warnings would be so voluminous as to defy any worth.

Because of this legal standard, Ethicon is entitled to defend the adequacy and contents of its warnings by referencing what licensed surgeons would know about the risks associated with pelvic floor surgery, including surgery using mesh augmentation. That necessarily includes information that a surgeon would learn through education, clinical training and professional

development. Since Ethicon's warnings are not to be judged by just what one particular surgeon knew, but by what commonly would be known to such physicians generally, Ethicon's experts can reference the common knowledge of surgeons in offering opinions concerning Ethicon's warnings. *Waterhouse v. R.J. Reynolds Tobacco Co.*, 368 F. Supp. 2d 432, 437 (D. Md. 2005), *aff'd*, 162 F. App'x 231 (4th Cir. 2006) ("expert testimony is required with respect to the state of common knowledge of smoking hazards during the smoking career of a plaintiff and that that testimony must be rendered by competent experts."); *Cruz-Vargas v. R.J. Reynolds Tobacco Co.*, 348 F.3d 271, 277 (1st Cir. 2003) (testimony regarding common knowledge is critical in failure to warn cases, and expert opinion concerning knowledge of average consumer was appropriate and relevant). Based upon this, it is wholly appropriate for Dr. Murphy to opine regarding which risks exist (or do not exist) associated with the Prolift and whether these risks were identified in the IFU or were otherwise generally known to pelvic floor surgeons.

Dr. Murphy is particularly equipped to offer such opinions. He relied on his extensive "training, education, experience, discussions with colleagues, and review of materials and the medical and scientific literature," as identified and set forth in his Report. *See* Ex. D, Murphy Prolift Report, at 2. Dr. Murphy specializes in disorders of the female pelvic floor and conducted approximately 1000 surgeries using the Prolift system. *Id*. at 1-2. His Report is clear that his opinions are based on the knowledge and experience obtained in his clinical practice as well as on peer-reviewed studies and randomized controlled trials. *Id*. at 17-26.

Dr. Murphy also trained other physicians on the use of Prolift, assisting them in both implantation and in assessing complications.

Q. Did you do Prolift® training? Did you train surgeons on the Prolift® procedure?

A. I did do some, yes.

Q. What type of training was that?

A. I did a number of cadaver labs both on Prolift® and Prolift+M®. I don't know how many. I would probably say somewhere in the range of 5 to 15, and then I also did some proctoring and some -- maybe a little bit of precepting as well.

***

Q. If surgeons encountered a complication and wanted to seek input from someone such as yourself, a precept or proctor, were they available to do such?

A. Absolutely.

Ex. 1, Murphy (11/30/12) Dep. Transcript at 504:24–505:7; 530:9-12.

As is made clear by his Report and testimony, Dr. Murphy's opinions rest not only on his experience, but on his review of the medical literature and peer-reviewed studies, and his experience in teaching medical professionals in the use of Prolift. This is a more than sufficient basis to permit him to opine concerning the risks of Prolift use and whether those risks were included in the IFU or otherwise known to pelvic floor surgeons. Accordingly, his testimony concerning the Prolift warnings should not be categorically excluded, as Plaintiffs argue.

II. What Ethicon "Knew" and "Thought" Has No Bearing On Dr. Murphy's Testimony Regarding His Experience with the Safety and Efficacy of the Prolift System.

Plaintiffs argue that "Dr. Murphy should be barred from rendering any opinions as to whether Ethicon acted reasonably or met the standard of care because he acknowledged in his November 30, 2012, deposition that he has no idea what Ethicon knew and thought as to the risks of the Prolift." Pls.' Mem. at 4. What Ethicon "knew and thought" has no bearing on Dr. Murphy's ability to review the available data and studies or analyze the amount of data available regarding the Prolift, and the safety, potential risks and efficacy of Prolift. What Ethicon "knew

and thought" has no relevance to Dr. Murphy's clinical experience with the safety and efficacy of the Prolift System in over 1,000 patients, experiences he has shared with other urogynecology physicians. Ex. D to Pls.' Mot., Murphy Prolift Report at 17-26. What Ethicon "knew and thought" cannot diminish his extensive experience in training and teaching the Prolift system and its potential risks and benefits to other surgeons.

III. Plaintiffs Provide No Basis for Excluding and/or Limiting Dr. Murphy's Other Opinions.

Plaintiffs further seek to exclude or limit Dr. Murphy's testimony in four additional categories: (1) the internal pre-market design and evaluation process (DDSA, FMEA) conducted by Ethicon for the Prolift System; (2) the French and US TVM Studies; (3) the Gynemesh PS Study; and (4) whether or not it was reasonable for Ethicon to decide that the Prolift System was safe and effective to be marketed. Pls.' Mem. at 5-6. Plaintiffs appear to believe such exclusion is proper because, again, Dr. Murphy could not testify concerning what Ethicon knew or relied upon in relation to certain studies. *Id*. And Plaintiffs incorrectly state that Dr. Murphy has no opinion on these subjects. But Dr. Murphy's Report does address the design of the Prolift System. Ex. D to Pls.' Mot., Murphy Prolift Report at 19-21, 26. The fact that he did not see internal Ethicon design documents in no way undercuts his opinions which are based on years of extensive clinical experience utilizing Gynemesh PS, the TVM, and the Prolift System and his review of the medical literature concerning the Prolift. Moreover, Plaintiffs simply disagree with his conclusions on these subjects, as the following exchange reflects:

> Q. You would want to see Ethicon have taken whatever steps were available to it to start to collect data so that that information could get to doctors as quickly as possible, and so also down the line, there would be a lot of data to be able to look back on and say we have a good idea of what's been going on, correct?

A. I think they were doing that in following TVM patients. Even though you seem to think there is a huge difference between the Prolift® kit and TVM, as a doctor, as an expert, I don't see a big difference there.

Q. Was there a difference in the instruments between TVM and Prolift®?

A. A small difference, yes.

Q. That's your understanding, it was a small difference?

A. Not my understanding. It's what I know.

Q. Do you think the tools, the instruments used in the TVM study were good instruments, good tools?

A. I think they were good. I think the Prolift® instruments were better for the procedure.

Ex. 1, Murphy (11/30/12) Dep. Tr. at 251:14– 252:20.

Likewise, Dr. Murphy's report clearly takes into account and addresses the French and US TVM studies, as well as the Gynemesh PS Study. *See* Ex. D to Pls.' Mot., Murphy Prolift Report at 17-19 (TVM Studies and Gynemesh PS Study); Ex. 1, Murphy (11/30/12) Dep. at 90:22–91:5; 437:23–438:19. Plaintiffs' repeated questioning regarding what Ethicon knew, thought or relied upon does not undercut Dr. Murphy's opinions regarding the safety and efficacy of the Prolift System — based upon his education and clinical experience, his extensive review of the literature and data concerning Prolift, as well as the materials he relied upon as set forth in his Prolift Report. A physician's "knowledge, experience, and review of scientific literature provide sufficiently reliable bases for his opinions under *Daubert*." *Eghnayem v. Boston Scientific Corp.*, 57 F. Supp. 3d 658, 714 (S.D.W. Va. 2014).

IV. Plaintiffs' Arguments Regarding Whether Dr. Murphy Relied Upon Various Materials Goes to the Weight of His Testimony, Not Admissibility.

Plaintiffs' argument that because Dr. Murphy did not read or rely upon every page of every item listed in the "Additional Materials" section of his Expert Report and Supplemental

Report, that he should be precluded from relying on any of them — including materials he did, in fact, consider and rely upon — is unpersuasive. Plaintiffs were not precluded from questioning Dr. Murphy about any materials identified in his Expert Report or Supplemental Report. *See* Pls.' Mem. at 6-7. They could have explored such lines of questioning at any point during his fourteen (14) hour deposition. There is no justification for excluding testimony at trial regarding materials Dr. Murphy reviewed and/or relied upon in preparing his report or those that he is familiar with in the course of his medical practice. Rather, "[i]f there are certain device-specific publications that [the expert] failed to review in preparing his expert report, the plaintiff is free to ask him about those publications on cross-examination." *Trevino v. Boston Scientific Corp.*, 2016 WL 2939521, *40 (S.D. W. Va. May 19, 2016); *see also Huskey v. Ethicon, Inc.*, 29 F. Supp. 3d 691, 735 (S.D. W. Va. 2014) (pelvic floor surgeon's "clinical experience and his review of the scientific literature" set forth a sufficient basis for his opinion and his "failure to review particular documents goes to the weight of his opinion, not its admissibility.").

As previously noted, Dr. Murphy's expert opinions do not exist in a vacuum. His personal knowledge and experience cannot be severed from his evidential support for his opinions here.

V. Dr. Murphy's opinions about the TVT and TVT-O warnings are admissible.

As they did so consistently throughout their Motion, Plaintiffs have failed to identify with any specificity precisely what opinions they seek to exclude. Pls.' Mem. at 7. The failure to clearly identify the allegedly inadmissible opinions they seek to exclude warrants denial of Plaintiffs' Motion.

Again, Defendants recognize that this Court has ruled that physicians may not use legal terms of art in testifying about product warnings. *Ramsey*, 2016 WL 2939526, at *2; *Hall*, 2015

WL 868907, at *10. Accordingly, Dr. Murphy will not offer the opinion that the TVT and TVT-O IFUs "adequately" warned of potential complications.

However, Dr. Murphy has implanted approximately 3000 midurethral slings. Ex. B to Pls.' Mot., Murphy TVT Report at 3. He cites peer-reviewed studies and medical literature throughout his TVT Report to support his opinions. *Id.* As this Court noted in *Winebarger v. Boston Sci. Corp.*, 2015 WL 1887222, at *15 (S.D. W. Va. Apr. 24, 2015), doctors may rely upon their clinical experience regarding product risks and benefits and thereafter compare their personal knowledge and observations with language of the product warnings and labeling. This Court has made clear that a physician can draw upon his clinical experience and review of relevant literature to give opinions on a product's safety and efficacy. *See Tyree v. Boston Scientific Corp.*, 54 F. Supp. 3d 501, 585 (S.D.W. Va. 2014) (finding that urologist with extensive clinical experience and relying on peer-reviewed literature could opine on the safety and efficacy of mesh products). A physician is qualified to make a comparison between "the risks he perceives that the [device] poses to patients" and whether the labels "convey these risks to physicians." *Winebarger*, 2015 WL 1887222, at *15 (finding expert qualified to give opinions on product labeling based on his clinical experience). Dr. Murphy does just that and is qualified to do so.

For the reasons discussed in *Winebarger*, the fact that Dr. Murphy has never drafted an IFU, *see* Pls.' Mem. at 7-8, does not preclude him from discussing what he, as a surgeon trained in the use of TVT and TVT-O, believes the risks of product use are and whether those risks are identified in the IFU or known to pelvic floor surgeons. *Winebarger*, 2015 WL 1887222, *6-7, 15 (finding expert qualified to provide opinion on IFUs based on clinical experience despite lack of familiarity with FDA rules or regulations for warnings).

Plaintiffs again overlook the substantial experience, education and training that Dr. Murphy relies upon in discussing the product warnings. Their argument is that any opinion he would have is "pure speculation" and based on his "personal standards." Pls.' Mem. at 7. But it is not pure speculation to discuss the risks known to him as a surgeon trained in the use of these devices. As noted by Dr. Murphy, his opinions are based on his professional experience "as someone who has dedicated their life to pelvic reconstructive surgery." Ex. 2, Murphy (10/9/18) Dep. at 204:23–205:3.

VI. Opinions based on Dr. Murphy's experience are proper.

Plaintiffs argue that Dr. Murphy should be precluded from opining that polypropylene does not degrade and that fraying mesh or particle loss would have no clinical significance for the patient. Pls.' Mem. at 8. The basis for their argument is that Dr. Murphy has not performed research on polypropylene degradation, published any articles related to polypropylene mesh or degradation, or examined explanted mesh under a microscope. Pls.' Mem. at 8. This Court has rejected similar attempts to limit such testimony from practicing urogynecologists like Dr. Murphy. *See Trevino v. Boston Scientific Corp.*, 2016 WL 2939521, at *45 (S.D. W. Va. May 19, 2016) (allowing expert to testify that he has not experienced mesh degradation, contraction, or a foreign body response in his extensive experience).

In *Mathison v. Boston Scientific Corporation*, this Court found that a board-certified urologist, Dr. Lonny S. Green, who had conducted nearly 3,000 sling procedures and practiced for twenty years, was qualified to opine that the mesh product does not shrink, contract, degrade, or cause systemic infections. No. 2:13-CV-05851, 2015 WL 2124991, at *27-28 (S.D. W. Va. May 6, 2015). This Court further found that the doctor's clinical experience and review of

scientific literature were sufficiently reliable bases in forming the opinion. *Id.* at *27.[2] Dr. Murphy's clinical credentials are virtually identical: he graduated from medical school in 1997 and began performing midurethral sling procedures during his residency; he has performed approximately 3000 midurethral sling procedures. *See* Ex. B to Pls.' Mot., Murphy TVT Report at 1-3. Like Dr. Green, Dr. Murphy has sufficient familiarity and experience with sling procedures, mesh slings generally, pelvic floor prolapse procedures, and the Gynemesh, TVT and Prolift devices in particular to provide reliable opinions on whether they are safe and effective, and whether they shrink, contract, or degrade. His opinions are not "assumptions," as Plaintiffs' suggest, Pls.' Mem. at 9, and are admissible.

Notwithstanding this, Dr. Murphy has additional experience related to biomaterials assessments. He has written book chapters regarding the use of mesh in pelvic floor surgery based upon his biomaterials assessment of mesh devices, including the TVT and TVT-O. Ex. 2, Murphy Dep. (10/9/18) at 209:9-210:20 (noting that book chapter "included a review of materials, their use in pelvic surgery, including suture, biologic grafts, xenografts, cadaveric grafts and synthetic grafts, particularly the synthetic grafts used in TVT and TVT-O."). He has taught professional education courses related to numerous aspects of mesh devices, including overall design, implantation instruments and the patient benefits that result from the design of the devices. *Id*. at 210:11-211:20. He has lectured regarding the product warnings and management of potential complications from the devices. *Id*. at 212:19-24. Dr. Murphy also has design

[2] *See also, In re C.R. Bard, Inc.*, 948 F. Supp. 2d 589, 612 (S.D. W. Va. 2013) (Goodwin, J.) (ruling that an expert was qualified to opine on product design and biomaterials because he had "extensive experience with pelvic floor disorders and the use of mesh to treat such disorders"); *Tyree v. Boston Scientific Corp.*, 54 F. Supp. 3d 501, 585 (S.D.W. Va. 2014) (permitting board-certified urologist with no stated "design" expertise to testify to the safety and effectiveness of mesh as he had "performed almost 3,000 sling procedures," and "cites numerous studies and academic papers throughout his expert report to support his opinion that the Obtryx is both safe and effective").

experience related to mesh devices, and has discussed such designs with medical directors and clinical engineers. *Id.* at 215:4–216:4; 216:15-21. Coupled with his extensive clinical experience and study of peer reviewed medical literature and studies, his opinions concerning degradation and fraying are admissible here.

CONCLUSION

For the reasons stated above, the Court should deny Plaintiffs' motion to exclude the opinions and testimony of Dr. Miles Murphy.

Respectfully submitted,

/s/ William M. Gage
William M. Gage (MS Bar No. 8691)
Butler Snow LLP
1020 Highland Colony Parkway
Suite 1400 (39157)
P.O. Box 6010
Ridgeland, MS 39158-6010
(601) 985-4561
william.gage@butlersnow.com

/s/ Susan M. Robinson
Susan M. Robinson (W. Va. Bar No. 5169)
Thomas Combs & Spann PLLC
300 Summers Street
Suite 1380 (25301)
P.O. Box 3824
Charleston, WV 24338
(304) 414-1800
srobinson@tcspllc.com

COUNSEL FOR DEFENDANTS

CERTIFICATE OF SERVICE

I certify that on this day, I electronically filed this document with the clerk of the court using the CM/ECF system, which will send notification of this filing to CM/ECF participants registered to receive service in this MDL.

/s/ William M. Gage
William M. Gage